

REMARKS

Claims 26-61 are pending. Of these claims, claims 32-61 are withdrawn.

Claims 26-32 and 52 are amended herein.

Claims 62-71 are newly presented.

Support for the present amendment is found in the specification as originally filed. More specifically, support for “apoptogenic” in claims 26 and 30 is found at least at page 16, lines 7-9; support for “immunogenic derivative” in claims 27 and 28 is found at least at page 4, line 14; and support for “substantially homologous recombinant derivative” in claim 62 is found at least at page 7, lines 6-7.

No new matter is introduced.

Applicants reserve the right to reintroduce cancelled subject matter, for example, in a later-filed continuing application.

Rejection of Claims under 35 U.S.C. §102(b) is Traversed

The Office rejected claims 26-31 as allegedly anticipated by Barnes (WO 01/10459). Office Action at page 2-4. In view of the foregoing amendment and the following remarks, the rejection is traversed.

According to the Office, “Barnes teach an isolated protein comprising the 55 kDa extracellular protein of *Photobacterium damsela subsp. Piscicida*.” Office Action at page 3, lines 1-2. Moreover, the Office asserts that “the structure of the protein, i.e., SEQ ID NO:2 ... is deemed inherent to the prior art composition which is obtained from the same species (*Photobacterium damsela subsp. Piscicida*), the same region within such species (extracellular) and has the same molecular weight (55 kDa) as the claimed composition.” Office Action at page 3, lines 16-21. According to the Office, “the burden of establishing non-anticipation by objective evidence is shifted to the Applicants.” Office Action at page 4, lines 3-5.

Applicants point out that, in addition to the above passages from Barnes cited by the Office, Barnes also states that “[s]ubsequent purification of the 55 Kda protein and sequencing have revealed three proteins in this region.” Barnes at page 16, lines 23-25. According to Barnes’ sequencing experiments, one protein is N-terminal blocked ... and,

therefore unable to obtain a sequence, however this fraction has strong Haemagglutinating activity.” Barnes at page 16, lines 25-29. As to the second and third proteins, Barnes specifically discloses their respective N-terminal sequences, however, neither sequence corresponds to Applicants’ isolated protein. Barnes at page 16, lines 30-35. Even with respect to size, Barnes teaches that of the two bands evident, “one [ran] close to 97KDa” and “[t]he other was smaller, running close to, but below, the 55KDa marker.” Barnes at page 13, lines 7-11. Therefore, the identity of the protein disclosed in Barnes is unclear.

Indeed, regarding the Office assertion that “the structure of the protein, i.e., SEQ ID NO:2 … is deemed [*inherent*] to the prior art composition,” Applicants point out that inherency cannot be established by mere possibilities or even probabilities. The fact that a certain result or characteristic may occur or may be present in cited art is not sufficient to establish the inherency of that result or characteristic. MPEP §2112. Barnes was unable to sequence one of three proteins that apparently were co-migrating (*i.e.*, “running close to, but below, the 55KDa marker”). Barnes at page 13, lines 10-11. And of the other two proteins that were in fact sequenced by Barnes, neither one corresponds to Applicants’ sequence.

Then, although it is not clear what protein is disclosed in Barnes, it is clear that Applicants’ claimed protein is distinct from the protein disclosed in Barnes. The instant specification, at page 3, lines 16-18, states that “[t]he 55kDa protein of the present invention is distinct from the so-called 55kDa ECP protein complex … disclosed in [Barnes], which in fact is nearer to 52kDa in size.” Further, as it relates to apoptogenic properties, the instant specification further points out at page 3, lines 22-25 that, “when antiserum raised against the [Barnes] 55kDa ECP complex was used to treat ECP preparations to remove this protein, the apoptogenic properties of the treated ECP preparation were unaffected.” Applicants point out that the 55kDa protein of the present invention has apoptogenic properties and is distinguishable by apoptosis assays such as that referenced by the instant specification at page 6, last line through page 7, line 3 (“A skilled person can easily test for absence of this protein in a strain by … replicating the apoptosis assay described in do Vale *et al.*, Fish and Shellfish Immunology 15 (2003): 129-144.”).

Interestingly, Barnes further states that “[t]he present inventor has determined that a protein (invasion or adhesion) expressed in the outer membrane under iron replete conditions is involved with [internalization]” Barnes at page 7, lines 15-19; emphasis added. Moreover, based on serological results, Barnes suggests “that the 55Kda ECP is a secreted version of the 97Kda OMP.” Barnes at page 16, lines 17-19.

Thus, Barnes could not possibly have anticipated Applicants’ claimed invention. Accordingly, the rejection is in error, therefore, withdrawal of the rejection is respectfully requested. Nonetheless, Applicants have amended claims 26 and 30 to recite “apoptogenic.” Moreover, newly presented claims 62-69 require the feature “recombinant.”

CONCLUSION

Applicants believe that all rejections have been traversed and that the claims are in condition for immediate allowance. Early notice to that effect is earnestly solicited.

The Examiner is invited to contact the undersigned at (202) 857-4507 with any questions she may have concerning this submission.

Respectfully submitted,

Date: March 26, 2009

By: 
Alireza Behrooz
Attorney for Applicants
Registration No. 60,882

Docket No. : VA/H-33271A

WOMBLE CARLYLE SANDRIDGE & RICE, PLLC
1401 Eye Street, NW, Seventh Floor
Washington, DC 20005

Office (202) 857-4507
Fax (202) 261-0042